REMARKS

Claims 1-7 remain pending. By the foregoing amendment, claim 2 has been amended to address a formal matter and claims 8-15, drawn to a non-elected invention, have been canceled without prejudice or disclaimer. Applicants expressly reserve the right to pursue the canceled subject matter in a divisional application pursuant to 35 U.S.C. § 120.

Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Office Action asserts that it is unclear whether the recited amounts of individual minerals are part of the total mineral amount or in addition to the previously named amounts of minerals.

By the foregoing amendment, claim 2 has been amended to clarify that calcium and phosphorous form part of the previously-recited "inorganic mineral" (which, in turn, forms part of the aforementioned "total minerals"). It is believed that amended claim 2 is properly definite. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

Claims 1-7 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action asserts that the claimed subject matter is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. This rejection is respectfully traversed.

The Office Action asserts, "[t]he specification lacks examples of treatment and does not disclose dosages, amounts, ranges, methods or modes of administration" and that "there is no commonality among the named disorders such that one would expect the method to be successful in each disorder based on another." Applicants respectfully disagree with the Office Action's characterization of the specification.

As discussed in the specification at page 4, lines 4-12, a first group of disorders including high blood pressure, stroke, obesity, kidney stones, colon cancer, breast cancer, head and neck tumors, premenstrual syndrome, postpartum depression, and hypertensive disorders of pregnancy, have been associated with inadequate intake of dairy products, and particularly the minerals present in dairy products. A second group of disorders including Type-2 diabetes, depression, asthma, inflammatory bowel disease, attention deficit disorder, migraine headaches, kidney disease, hypercholesterolemia, congestive heart failure, and immune deficiency have been clinically associated with the first group of disorders and exhibit similar pathophysiologic mechanisms. Contrary to the Office Action's assertion that "there is no commonality among the named disorders," the disorders have been recognized as exhibiting similar pathophysiologic mechanisms.

With respect to dosages and effective amounts, exemplary amounts of milk mineral in food products (*e.g.*, dosages) are described at page 6, lines 22-27. In addition, Examples 1-6 show specific examples of food products containing therapeutically effective amounts of milk mineral in their respective servings. The Office Action's assertion that methods or modes of administration are not identified is particularly puzzling. The fortified food products, containing milk mineral, are of course administered in the same manner that a corresponding non-fortified food product would be consumed.

In any event, the lack of enablement rejection is facially defective at least because the Office Action fails to identify any objective evidence to question the asserted utility. The Federal Circuit has made clear that where a specification asserts that a composition has a specific utility, there exists a presumption that the specification is enabling for a claim directed to

administering the composition for the asserted utility. The USPTO therefore bears the burden of establishing objective evidence to reject claims for lack of enablement. *In re Brana*, 34 USPQ2d 1436 (Fed. Cir. 1995). Such evidence must show *prima facie* that undue experimentation would have been required to make and use the claimed invention. Because the rejection is based only on conjecture and is entirely devoid of objective evidence, the lack of enablement rejection is facially defective and should be withdrawn. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

Claims 1-3 and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Govers et al. Claims 1-3 and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mitsubori et al. Claims 1, 3, 4, and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Howard U.S. Patent 4,237,118 ("Howard"). Claims 1-3 and 7 stand rejected under 35 U.S.C. §§ 102(a) and (e) as being anticipated by Girsh U.S. 2001/0022986 ("Girsh"). Claims 1-3 and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Nakagawa et al. U.S. Patent 5,185,166 ("Nakagawa"). Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Govers, Mitsubori, or Howard in view of Girsh and/or Nakagawa. Each of these rejections is respectfully traversed.

Govers is cited as describing administering milk mineral to inhibit colon cancer. Govers actually describes a study in which one group of rats was fed a milk mineral diet composed of 650 g/kg diet lactase-treated whole milk powder (see page 95, "Materials and Methods"). Govers concludes, "The mechanism of milk mineral is similar to that of calcium carbonate and calcium phosphate, indicating that the antiproliferative effect of milk mineral is mediated by its calcium content. . . . further research is warranted on the mechanism and the physiological

relevance of the observed protective effects of milk mineral in humans." (page 99, second column). Govers essentially concludes that milk mineral is no better than calcium carbonate or calcium phosphate for treating colon cancer. Gover's conclusion would have led persons skilled in the art toward using these simpler forms of calcium (calcium carbonate or calcium phosphate) because Govers attributes physiological effects to calcium content alone. In any event, Govers clearly does not describe or suggest administering a food product containing a therapeutically effective amount of milk mineral, as claimed in claim 1. Govers therefore fails to anticipate or suggest the invention of claims 1-7.

Mitsubori is cited as describing a whey mineral diet for treating hypertension. At page 94, Mitsubori actually discloses whey mineral concentrate, which is recognized in the art as distinct from milk mineral, as is presently claimed. Milk mineral is a term of art describing a complex, obtained by extracting whey or milk, which contains a balanced form of calcium, phosphorous, potassium, magnesium, and zinc, and which exhibits high calcium bioavailability. *See,* specification, p. 4, line 24 through p. 5, line 12. Mitsubori does not describe milk mineral, let alone administering a food product containing a therapeutically effective amount of milk mineral. Mitsubori therefore fails to describe or suggest the invention of claims 1-7.

Howard is cited as disclosing supplements containing dried skimmed milk, potassium, magnesium, phosphorous, zinc, and protein for treating obesity. Howard does not describe milk mineral, let alone administering a food product containing a therapeutically effective amount of milk mineral, as set forth in claim 1. Howard therefore fails to describe or suggest the particular method claimed in claims 1-7.

Girsh is cited as describing compositions of milk or whey permeate said to be rich in vitamins and minerals, which are combined with flavoring agents to form beverages. Girsh describes milk or whey permeate in contrast to milk mineral, as presently claimed. Milk or whey permeate is distinct from milk mineral, and is recognized in the art as such. For at least this reason, Girsh fails to describe or suggest the particular method claimed in claims 1-7.

Nakagawa is cited as disclosing milk mineral concentrate added to drinks. The Office Action concedes that neither Girsh nor Nakagawa discloses a method of treating any of the disorders identified in claim 1 by administering a food product containing a therapeutically effective amount of milk mineral. Nevertheless, the Office Action contends that because the claims embrace prophylactic treatments, Girsh and Nakagawa anticipate the claims by virtue of their disclosures of administering fortified compositions for dietary consumption.

Applicants respectfully submit that the Office Action's position with respect to Girsh and Nakagawa is at direct odds with Federal Circuit precedent. The Federal Circuit recently held in *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1334 (Fed. Cir. 2003) that claims directed to a particular method of treatment require an appreciation of the need for the specified treatment or prevention. ("[The] claims are properly interpreted to mean that the combination of folic acid and vitamin B_{12} must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia") (emphasis added). Similarly, in *Rapoport v. Dement*, 254 F.3d 1053, 1061 (Fed. Cir. 2001), the Federal Circuit found no anticipation where the prior art did not describe administering a compound "with the intent to cure the underlying condition." Consequently, the Office Action is incorrect in suggesting that it is not necessary for the prior art to appreciate the need of treating or preventing the claimed disorders.

None of the cited documents, whether taken alone or in any combination, describes or suggests a method of treating any of the disorders listed in claim 1 by administering a food product containing a therapeutically effective amount of milk mineral, as claimed in claim 1. The dependent claims 2-7 specify further limitations and are allowable over the cited references for at least the same reasons that claim 1 is allowable. Reconsideration and withdrawal of each of the §§ 102 and 103 rejections is respectfully requested.

Claims 1-7 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 19-34 of co-pending Application No. 10/371,534. The Office Action concedes that the allegedly conflicting claims are not identical, but asserts that they are not patentably distinct because both sets of claims embrace a method of treating obesity with a composition containing milk mineral in orange juice.

A double patenting rejection is proper only where a claimed invention would have been obvious over the claims of another patent or application. *In re Kaplan*, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986). Mere domination or overlapping of claims does not necessarily give rise to obviousness-type double patenting. *Id.*

The Office Action contends that both sets of claims embrace common subject matter. However, the Office Action does not explain (or even assert) that claims 1-7 would have been obvious over the claims of the co-pending '534 application – which is the appropriate inquiry for obviousness-type double patenting. Claims 19-34 of the '534 application are directed to treating obesity by administering a nutritional composition containing milk mineral and protein component, whereas the present claims are directed to treating various disorders by

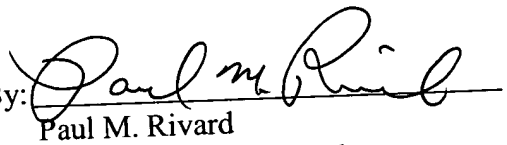
administering a food product containing milk mineral. It is respectfully submitted that the Office Action has failed to show that the claims of the two applications are not patentably distinct. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

CONCLUSION

In view of the foregoing, favorable reconsideration and allowance of the subject application are respectfully requested. The Examiner is invited to telephone the undersigned at the number listed below if doing so would be helpful to resolve any outstanding matters.

Respectfully submitted,

Date: March 16, 2004

By: 
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